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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 715,983	11 20 2000	Brett P. Moma	ISPH-0519	6803

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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 07 30 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

File

# Advisory Action

Application No.  
09/715,983

Applicant(s)  
Monia et al

Examiner  
Jane Zara

Art Unit  
1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jul 7, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s):  
Scope of enablement rejections of claims 24, 26-28, 30, 31

4. ☒ Newly proposed or amended claim(s) 24, 26-28, 30, and 31 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Please see attached. The enablement rejection is maintained for claims 40, 42-44, 46 and 47.

6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 24, 26-28, 30, and 31

Claim(s) objected to: None

Claim(s) rejected: 40, 42-44, 46, and 47

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_


10. Other: \_\_\_\_\_

RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER

Art Unit: 1635

*Attachment*

Claims 40, 42-44, 46 and 47 are rejected for lacking enablement over the scope claimed for the reasons of record set forth previously in the Office actions mailed November 19, 2002 and May 7, 2003, Paper Nos. 9 and 11 respectively. Applicants argue that it would not be unpredictable to prevent or delay the onset of increasing insulin or blood glucose levels in a human comprising administration of antisense targeting PI3K p85 because the instant disclosure teaches a decrease in blood glucose or insulin levels in appropriate mouse models, and the extrapolation from decreasing blood glucose or insulin levels in a mouse model for up to two weeks following weekly administration of antisense, to prevention of any and/or all increases in blood glucose or insulin levels for an undefined period following administration of antisense is reasonable. Contrary to Applicants' arguments, the observed decrease in blood glucose or insulin levels following administration of antisense is not predictive of the ability to prevent or delay increasing blood glucose or insulin levels in an organism for an undefined period of time comprising administration of anti- PI3K p85 antisense. Therefore the enablement rejection is maintained.

  
RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER